UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

ALEXANDRIA DIVISION

ROBERT L. SALIM CASE NUMBER: 19-CV-00442

VERSUS JUDGE: DRELL

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY, ET AL

MAGISTRATE JUDGE: PEREZ-MONTES

SUBMISSION BRIEF OF BEHALF OF ROBERT L. SALIM

Plaintiff, ROBERT L. SALIM, files his submission brief out of time and prays for an Order from this Court allowing the late filing of this brief on the merits.

STATEMENT OF THE CASE

ROBERT L. SALIM purchased a policy of group health insurance from LOUISIANA HEALTH SERVICE AND INDEMNITY COMPANY d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA with an effective date of May 1, 2009. This policy was purchased for all of the employees of ROBERT L. SALIM for which he paid an annual premium in excess of One Hundred Thousand and No/100 (\$100,000.00) Dollars. SALIM was diagnosed with throat cancer in September, 2018 and sought treatment from MD Anderson Cancer Center. Following is a time line of events relevant to this claim:

- 10/10/18 Pre-Authorization Request from MD Anderson was sent to Blue Cross/Blue Shield of Louisiana (BCBSLA) (AR 120-129)
- 10/12/18 BCBSLA mailed a letter to Salim denying authorization for Proton Treatment Delivery on the basis that same was not medically necessary (AR

130-134 - AIM Specialty Health ["AIM"] assists in the management of BCBSLA health benefits plans - AIM is an independent company that provides utilization management for certain services on behalf of BCBSLA)

- 10/12/18 BCBSLA also denied authorization for special radiation treatment procedure and guidance for localization of target delivery of radiation treatment delivery on the basis that same was not medically necessary (AR 135-144)
- 10/17/18 Salim sent a letter to Juanita Rodriguez of BCBSLA applying the denial of coverage by BCBSLA (AR 157)
- 10/20/18 BCBSLA upheld the denial of the Pre-Authorization Request from MD Anderson Cancer Center on the basis that the treatment was not medically necessary (AR 193-219)
- 10/30/18 MD Anderson Proton Therapy Center filed a second level appeal requesting an urgent external review by an independent review organization (AR 227-270)
- 10/31/18 Medical Review Institute of America, LLC mailed correspondence to Robert Salim stating that the prior denial of the requested Proton Beam Therapy was upheld (AR 271-275)

LAW AND ARGUMENT

Plaintiff acknowledges that the group health plan issued to SALIM is an ERISA policy and that said plan grants BLUE CROSS full "discretionary authority" to determine the eligibility for benefits and/or to construe and interpret the terms of the Plan except in those cases where the determination by BLUE CROSS is deemed to constitute an abuse of discretion.

Plaintiff shows that in the instant case the denial of insurance coverage for the Proton Beam Therapy recommended by MD Anderson was an abuse of discretion.

BLUE CROSS's denial of coverage was on the basis that the Proton Beam Therapy recommended by MD Anderson was not "Medically Necessary." The term "Medically Necessary" is defined in the Plan at Pg. 35 of the Administrative Record:

The Plan fully defines "Medically Necessary" at AR 035 as:

Medically Necessary (or Medical Necessity) - Healthcare services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, or Provider, and not more costly than alternative services, treatment, procedures, equipment, drugs, devices, items or supplies or sequence thereof and that are as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

Interestingly, SALIM filed an appeal to BLUE CROSS on October 17, 2018, and a denial was received on October 20, 2018. Thereafter, MD Anderson instituted a second level appeal on behalf of SALIM on October 30, 2018 and the so called independent review

by Medical Review Institute of America denied the appeal the following day on October 31, 2018. It is inconceivable that Medical Review Institute of America, LLC could have given proper consideration to this appeal set forth in the nine (9) page letter from Dr. Clinton Fuller, Assistant Professor in the Department of Radiology Oncology at the University of Texas MD Anderson Cancer Center (AR 229-237). In this nine (9) page letter Dr. Fuller specifically addresses BLUE CROSS's contention that Proton Beam Therapy is "not medically necessary." On Pg. 2 of Dr. Fuller's letter he points out:

"In reviewing the BCBS-AIM's Radiation Therapy Criteria, we are struck by the fact that out of the nearly 50 reference articles used to support the denial, only 3 relate to head and neck cancer. Surprisingly, ALL 3 articles from AIM's own guidelines specifically endorse the use of Proton Therapy and report 'clinically significant reductions of toxicity, better outcomes, and fewer Gtube insertions!'

Ironically, the most recent denial was based AIM Clinical Guidelines Proton Radiation Therapy (3/12/18) which includes the 2017 American Society for radiation oncology (ASTRO) model policy. This policy has been updated in 2017 to specifically include Proton Beam Therapy as both appropriate and medically necessary for exactly Mr. Salim's diagnosis, advanced head and neck cancer that involves the base of the skull. The policy supports the use of PBT for head and neck cancers. They go on to say Proton Therapy is medically necessary 'in instances where sparing the surrounding normal tissue cannot be adequately achieved with Photon-Based Radial Therapy and is of added clinical benefit to the patient.'

Additionally, a guideline that was glaring omitted from the policy used to deny this case is the 2017 National Comprehensive Cancer Network (NCCN) Head and Neck Guidelines. These guidelines were also revised to declare Proton Beam Therapy as being medically necessary, and the standard of care for head and neck patients. This is especially notable because updted NCCN Guidelines

for other disease sites ARE included in the knowledge base.

As you can see from the enclosed reference list, most of the evidence documenting Proton's superiority for Head and Neck cancers has been published from 2014 to present. The omitted guidelines (NCCN) which are considered the industry standard, have been included along with the references in the attached enclosures."

Also included in Dr. Fullers' letter (AR 232, Pg. 3)
Dr. Fuller stated:

"The main challenge with Mr. Salim's case and why his case is unique requiring specialized care is there is massive oral disease with nodal spread including retropharyngeal nods at the base of skull. It is imperative we minimize radiation damage to the oral cavity to maintain swallowing, breathing, and proper saliva production, as well as preventing mandibular necrosis. This will minimize acute and chronic oral side effects and ultimately prevent additional risks for feeding tube placement (which is an immediate burden to him and the cost to you the insurer)."

In Dr. Fuller's letter at pp. 3 and 4 (AR 232-233) he pointed out that ASTRO's model policy for PBT, which is included in the policy used to deny this particular case, was updated to include Mr. Salim's condition as a Group 1 disease site, meaning Proton Beam Therapy is medically necessary in this scenario.

CONCLUSION

It is apparent from the foregoing that BLUE CROSS used outdated medical literature to determine that PBT was not medically necessary for the treatment of Mr. Salim's throat cancer. BLUE CROSS's reliance upon outdated literature is arbitrary and

capricious and the decision of the Plan Administrator should be reversed.

Respectfully submitted,

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BY: s/Ronald E. Corkern, Jr.

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Attorney for Salim

<u>CERTIFICATE</u>

I hereby certify that a copy of the above and foregoing has been served upon all attorneys of record by depositing a copy of same in the U. S. Mail, postage prepaid and properly addressed, this 8^{th} day of December, 2020.

_s/Ronald E. Corkern, Jr.
OF COUNSEL